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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,783	11/03/2003	Charles William Rowe	900122.437D1	5511

500 7590 09/08/2006

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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/700,783	ROWE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02/03/04</u> .  | 6) <input type="checkbox"/> Other: ____                                     |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the second substance" in line 2. There is insufficient antecedent basis for this limitation in the claim. Neither claim 1 nor claim 7 recite said limitation.

Claims 14 and 15 are rejected for failing to further limit the subject matter of claim 12. Claim 12 is a product claim. Applicant is required to cancel the claims, or amend the claims to place them in proper dependent form, or rewrite the claims in independent form.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Cima et al. US 5,490,962.

Cima discloses a method for making implantable medical devices for controlled release of bioactive agent, the method comprising forming an implantable device by applying a layer of polymer powder, applying a binder layer on top of the first powder layer, and repeat these steps until the desired shape is obtained (column 4, lines 1 through column 5, lines 1-7; examples; and claims). The device further comprises bioactive agent incorporating into the solvent or binder (column 10, lines 1-15). Bioactive agent can be in different amount, or different combinations, in different layers or within different regions of one or more layers (different pattern) (column 10, lines 31-59). Bioactive agent includes protein, peptides, nucleic acids, and active pharmaceutical agent (column 9, lines 45-67).

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Sherwood et al. US 2003/0114936 A1.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Sherwood discloses a method for manufacturing an implantable device comprising depositing a layer of powder, dispensing a suspension of a binder liquid onto the powder layer, allowing the layers to dry, and repeating these steps if needed (paragraphs 0080, 0081, 0088 and 0131). The suspension of binder further includes biologically active materials, such as protein, ceramics, and API (paragraphs 0104, 0107, 0110 and 0143-0153). The implantable device is suitable as bone or cartilage implant (paragraphs 0069-0071). Sherwood further teaches the method of manufacture using 3DP with individual solenoid valves (paragraphs 0035-0038).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cima et al. US 5,490,962, in view of Roberts et al. US 6,458,769.

Cima is relied upon for the reason stated above. Cima does not explicitly teach some of the API is amorphous.

Roberts teaches it has been known that amorphous drug possesses far greater solubility than the crystalline form (column 2, lines 13-27). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cima using amorphous active agent in view of the teaching of Roberts,

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because Roberts teaches the advantageous results in the use of drug in amorphous form over drug in crystalline form, e.g., distinct dissolution characteristics and distinct bioavailability, because Roberts teaches mixture of amorphous and substantially crystalline forms of drug exhibit increase in solubility and stability (column 3, lines 48-62; and column 4, lines 54-67), and because Cima teaches drug in any form that remains stable and chemically and retain biological activity (column 9, lines 45-57).

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cima et al. US 5,490,962, in view of Jang et al. US 6,471,800.

Cima is relied upon for the reasons stated above. Cima does not teach dispensing suspension through a solenoid-operated valve onto powder.

Jang teaches a layer-additive method and apparatus for freeform fabrication of 3-D objects. The apparatus comprising dispensing means including solenoid valve (column 6, lines 31-38; and claims). Thus, it would have been obvious to one of ordinary skill in the art to use the solenoid valve as a dispensing means in view of the teaching of Jang, because Jang teaches an improved layer-additive method and apparatus for producing a 3-D object, and because Cima teaches the use of 3-D printing apparatus comprising multi-dispensing means.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sachs et al., Fink et al., Yuan et al., and Layrolle et al. are cited

as of interest for the teachings of three-dimensional printing, and coating medical/implantable device.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S. Tran  
Patent Examiner  
Art Unit 1615